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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION

This Documents Relates to All Cases

Case No. 3:13-MD-02452-AJB-MDD

DEFENDANTS AMYLIN PHARMACEUTICALS, LLC AND ELI LILLY AND COMPANY'S MOTION TO STRIKE OR SEAL CONFIDENTIAL INFORMATION IN CERTAIN DOCUMENTS ATTACHED TO PLAINTIFFS' PAPERS RELATED TO THE DEFENSE OF PREEMPTION.

Hon. Anthony J. Battaglia

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

OTHER AUTHORITIES

RULES

I. INTRODUCTION

Defendants Amylin Pharmaceuticals LLC ("Amylin") and Eli Lilly and Company ("Lilly") respectfully move the Court to strike or seal competitively sensitive and confidential information in several documents attached to Plaintiffs' submissions related to preemption. As set forth below, and as explained in the accompanying Declarations of Amy J. Laurendeau and Matthew J. Hamilton, the documents at issue incorporate, reference, and rely upon confidential materials, which were properly designated as "confidential" or "attorneys' eyes only" pursuant to the Parties' agreed-upon Amended Protective Order ("Protective Order").[1] To the extent that these documents are irrelevant to the Court's resolution of the preemption issue, cumulative, or unnecessary, Amylin and Lilly respectfully request that the Court strike these documents from the record. In the alternative, Amylin and Lilly respectfully move the Court to seal carefully limited portions of certain documents to protect their competitively sensitive and confidential information.

The Protective Order reflects the Parties' mutual understanding and agreement that the materials at issue in this litigation—"not only those items or things which are expressly designated as Confidential, but also all copies, excerpts, and summaries thereof, as well as testimony, oral communications, and other work product containing Confidential information or information derived therefore"—reflect confidential and proprietary regulatory submissions, trade secrets, and manufacturing information that should not be subject to disclosure (hereinafter

[1] The Court previously struck from the public docket one of the documents at issue, the Report of Dr. David Madigan, after plaintiffs filed it in connection with their service of expert reports relating to preemption.

"Confidential Documents").[2] The Protective Order underscores the fact that, outside this litigation, the MDL Defendants are fierce competitors—both with each other and with companies not part of this MDL—in a highly competitive market for diabetes medicines. Simply put, the Protective Order is designed to ensure that Confidential Documents are not subject to unfettered disclosure so as to protect the Defendants from the risk of significant competitive harm.

While Defendants did not attach or rely upon any confidential documents in their Motion for Summary Judgment on preemption grounds, Plaintiffs submitted a veritable mountain of Defendants' Confidential Documents as exhibits to their affirmative motion for Summary Judgment on Defendants' Preemption affirmative defense, their Response to Defendants' Motion for Summary Judgment and their Reply in Support of their affirmative Motion, in connection with what is, at base, a legal question.[3] In addition to documents designated confidential by Defendants, Plaintiffs attach reports of many of their experts designated not for preemption – the subject of the motions before the Court – but rather for general causation purposes, that cite to or disclose information designated confidential by defendants.

For the reasons that follow, and as set forth in the accompanying Declarations, the confidential attachments to plaintiffs' submissions should be stricken from the record. In the alternative, there are compelling reasons to keep

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[2] *See* Protective Order at § 1(f). The Confidential Documents at issue in this motion constitute Confidential Discovery Material as defined by the Protective Order. *See* Protective Order at § 1(c).

[3] The Court has made clear (twice) that "Plaintiffs' assertions that there were 'reasons to believe [pancreatic] cancers were not correctly reported and were under-reported' and that information was 'withheld by Defendants from the FDA' are fraud-on-the-FDA claims expressly preempted by *Buckman*." *E.g.*, Order Denying Plaintiffs' Motion to Compel Discovery of Adverse Event Source Documents and Databases, Document 554, 3:13-md-02452-AJB-MDD, 4.

this material confidential, [4] and Amylin and Lilly request that certain carefully limited portions of the documents at issue be redacted. Exhibits 4, 8, 9, and 11 to the Declaration of Ana C. Reyes in Support of Merck Sharp & Dohme Corp.'s Motion to Seal the Parties' Summary Judgment Memoranda on the Affirmative Defense of Preemption and Accompanying Exhibits are proposed public versions of Plaintiffs' Exhibits which reflect these limited redactions of Amylin's and Lilly's confidential material, as well as those identified by defendants Merck and Novo Nordisk in their Motions to Seal.

II. ARGUMENT

While the Ninth Circuit recognizes a presumption of public access to judicial records in the summary judgment context, there are compelling reasons why selected portions of the documents at issue should be sealed.[5] Where there are compelling reasons that outweigh the public policies favoring disclosure, such documents can be protected and preserved under seal. *See In re Midland Nat'l Life Ins. Co. Annuity Sales Practices Litig*. v. *Allianz Life Ins. Co. of N. Am.*, 686 F.3d 1115, 1119 (9th Cir. 2012); *Foltz,* 331 F.3d at 1155. Confidential materials are

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[4] While the Declarations of Amy J. Laurendeau and Matthew J. Hamilton each address specific portions of the Expert Reports, Amylin and Lilly, as alliance partners, share a common interest in the confidential nature of their documents and each relies upon and adopts the rationale offered by the other.

[5] Plaintiffs' Motion for Summary Judgment arguably is not a dispositive motion in that, even if granted, it will not dispose of the litigation. To the contrary, it seeks to strike a single affirmative defense – federal preemption. The more appropriate standard to apply to the exhibits attached thereto may be "good cause," which, as demonstrated below, defendants unquestionably satisfy here. *See Kamakana v. Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006) (stating the good cause standard will "suffice [] to warrant preserving the secrecy of sealed discovery material attached to nondispositive motions") (citing *Foltz v. State Farm Mut. Auto. Ins. Co.,* 331 F.3d 1122, 1135 (9th Cir. 2003) and *Phillips v. General Motors Corp.,* 307 F.3d 1206, 1213 (9th Cir. 2002)) (noting that the Ninth Circuit has "carved out an exception to the presumption of access" to judicial records for a "sealed discovery document [attached] to a non-dispositive motion," such that the "usual presumption of the public's right of access is rebutted"); *see also* Fed. R. Civ. P. 26(c); Protective Order, § 11(c).

shielded from public disclosure when "such court files might [] become a vehicle for improper purposes." *See, e.g., Algarin v. Maybelline*, No. 12-cv-3000, 2014 U.S. Dist. LEXIS 23882, 6-7 (S.D. Cal. Feb. 21, 2014) (quoting *Pintos v. Pacific Creditors Ass'n*, 605 F.3d 665, 669 (9th Cir. 2010)). Such improper purposes include potential use "to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." *Id.* at 7-8.

A. Defendants' Confidential Documents And Information Are Irrelevant To Preemption And Should Be Stricken.

According to Plaintiffs, "Defendants have never submitted a pancreatic cancer CBE to FDA. Without such proof, they cannot meet the 'clear evidence' standard." *See* Plaintiffs' Memorandum in Opposition to Defendants' Motion for Summary Judgment at 16. If this were so, Defendants' Confidential Documents would be, *a priori*, irrelevant—nothing in Defendants' Confidential Documents could change the simple fact that none allege that any has attempted to add a pancreatic cancer warning via CBE.

To the extent that Plaintiffs intend to use Defendants' Confidential Documents to argue that Defendants misreported or under-reported information to FDA, the Court has already spoken to the irrelevancy of such arguments to the issue of preemption. *See* Order Denying Plaintiffs' Motion to Compel Discovery of Adverse Event Source Documents and Databases, 8 (MDL Doc. No. 554) ("[T]he Court does not consider Plaintiffs' allegations of misreporting or under-reporting relevant to a preemption analysis").

B. Disclosure Of The Confidential Material Cited In Plaintiffs' Papers, Which Include Internal Emails And Discussions Of Incomplete, Preliminary Safety Evaluations, Would Harm Patients By Raising Undue Alarm About A Potential Safety Issue That FDA Has Recently Discredited.[6]

Diabetes is a public health crisis, and FDA has recognized that incretin-based therapies are an important treatment for managing the disease. Numerous medical societies have stated that the available data do not justify withholding incretin-based therapies from diabetic patients. *See* American Diabetes Association, *ADA/EASD/IDF Statement Concerning the Use of Incretin Therapy and Pancreatic Disease*, 2 (June 28, 2013) (noting there is insufficient information regarding incretin-based therapies and pancreatic disease to modify current treatment recommendations) (attached as Ex. C to Hamilton Declaration). There is a strong public interest in ensuring that patients and their physicians have access to accurate information about such therapies and are not confused by preliminary and incomplete statements in documents taken out of context.

The pancreatic safety of incretin-based therapies is an issue that has permeated the popular press. *See, e.g,* Andrew Pollack*, A Lone Voice Raising Alarms*, N.Y. Times, May 31, 2013, at B1 (attached as Ex. D to Hamilton Declaration). Indeed, both FDA and EMA recognized the media's focus on the issue as well: "Both agencies agree that assertions concerning a causal association

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[6] As has been described, the FDA and EMA recently and jointly published an article expressing their view that "current knowledge [regarding pancreatitis and pancreatic cancer] is adequately reflected in the product information or labeling" of incretin-based drugs. For its part, FDA's conclusion was based on an independent, year-long, "comprehensive evaluation" of "multiple streams of data." Such data included data from "more than 200 [clinical] trials, involving approximately 41,000 participants," and "more than 250 toxicology studies conducted in nearly 18,000 healthy animals[.]" *See* Amy G. Egan et al., *Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment*, 370;9 N Engl J Med 794, 796 (2014).

between incretin-based drugs and pancreatitis or pancreatic cancer, as expressed recently in the scientific literature and in the media, are inconsistent with the current data." *See* Amy G. Egan et al., *Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment*, 370;9 N Engl J Med 794, 796 (2014) (attached as Ex. E to Hamilton Declaration). Publication of partial safety information creates an atmosphere in which patients can become frightened off their medications and which interferes with the doctor-patient relationship. *Cf.* Judyth Pendell, *The Adverse Side Effects of Pharmaceutical Litigation,* AEI-Brookings Joint Center For Regulatory Studies (2003) (reporting physicians' refusal to prescribe and patients' refusal to take appropriately prescribed medications after learning medications were subject to product liability litigation) (attached as Ex. F to Hamilton Declaration).

With specific regard to the limited portions of the documents at issue, Amylin and Lilly respectfully offer the following rationale for their continued sealing.

In paragraph 8 of his Preemption report, Dr. Madigan refers to a confidential internal email discussion between Amylin and Lilly employees regarding a confidential regulatory response.[7] Laurendau Declaration at 4a; Hamilton Declaration at 9. The document was designated confidential when produced. This discussion, crucially, does not represent the full safety review and analysis that Amylin and Lilly undertook to assess the pancreatic safety of Byetta. Divorced from materials that demonstrate appropriate meaning, interpretation, and final conclusions, this confidential information would provide selective, distorted information to patients who take Byetta (and other incretin-based therapies) to manage their diabetes.

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[7] Paragraph 8 of Dr. Madigan's Preemption report appears verbatim at paragraph 9 of his General Causation report.

In his general causation report, Dr. Carson likewise cites cherry-picked aspects of confidential-designated Lilly studies in paragraphs IV.C and VII.E.2 in support of Plaintiffs' assertion that Defendants have not appropriately reported or interpreted the results of their clinical trials. Hamilton Declaration at 11, 12. These snippets, taken out of context, do not fairly represent the studies cited. Divorced from materials that demonstrate appropriate context, meaning, interpretation, and final conclusions, this confidential information would provide selective, distorted information to patients who take Byetta (and other incretin-based therapies) to manage their diabetes.

C. Substantial Competitive Harm Could Result From Disclosure Of Defendants' Confidential Material.

The documents that Dr. Madigan references and discusses also include internal communications that reflect the confidential process that Defendants use to evaluate and analyze post-marketing safety data. FDA mandates no set procedure or methodology for the evaluation of safety data for pharmacovigilance purposes. *See* U.S. Food and Drug Administration Guidance for Industry – E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (attached as Ex. A to Hamilton Declaration). Rather, "judgment should be used in such situations to determine whether the data reflect a meaningful change in [Adverse Drug Reactions] occurrence or safety profile and whether an explanation can be proposed to such a change (*e.g.*, population exposed, duration of exposure)." *See id.* Accordingly, each company's methodology reflects a proprietary process, and so documents that reflect that process, leading to the preparation of confidential PSUR submissions, deserve the same level of confidentiality that the agency accords final PSURs.

In paragraph 33 of his Report, Dr. Madigan discusses Amylin's confidential internal pharmacovigilance and safety analyses regarding pancreatic cancer.[8] *See* Laurendeau Declaration at 4b. It is axiomatic in the pharmaceutical industry that there exist competitors who can derive some commercial benefit from data access. *See, e.g.*, *Public Citizen Health Research Group v. NIH*, 209 F. Supp. 2d 37, 47 (D.D.C. 2002). In this MDL alone, there are four competitors in the marketplace, and there are numerous other manufacturer competitors in the diabetes arena not involved in the instant ligation. Indeed, competitors routinely attempt to acquire safety and efficacy data by petitioning FDA under the Freedom of Information Act ("FOIA"). *See* Orrin Hatch, *Refinements Are Needed To Stop Abuses*, ABA Journal 556, 557 (May 1983) (noting that 85% of the FOIA requests received by FDA are initiated by pharmaceutical companies, "many of whom are seeking their competitors secrets"). FDA, for its part, recognizes that safety and efficacy data constitute "confidential commercial information," and are therefore exempt from FOIA disclosure requirements. *See* 39 Fed. Reg. 44602, 44634 (Dec. 24, 1974) (release of data upon request would allow 'me-too' drugs to be marketed immediately). In an industry where it takes ten-plus years and $2.55 *billion* just to gain market approval for a new drug—even the smallest amount of competitive intelligence can provide a sizable advantage (*i.e.*, better knowing where or where not to invest resources). *See generally* Joseph A. DiMasi, Tufts Center for the Study of Drug Development, *Briefing: Costs of Developing a New Drug* (November 18, 2014) (noting that about $1.1 billion is spent before the first human enters a clinical trial).

[8] The confidential content in paragraph 33 of Dr. Madigan's Preemption report appears at paragraph 13 in his General Causation report.

D. There Is No Compelling Public Interest That Outweighs Potential Public Harms To Patients Who Use Incretin-Based Therapies And The Potential Competitive Harms To Defendants.

Because the Court has not yet determined what materials it will rely on to decide Plaintiffs' motion, no one knows which – if any – of the exhibits attached to Plaintiffs' motion will become judicial documents by affecting the resolution of the dispute on the merits. *See, e.g.*, *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 143 (2d Cir. 2004) ("There is no established presumption of access" to information not relied upon by the court). Thus, the Confidential Documents do not currently aid "the public interest in understanding the judicial process." *See, e.g.*, *Cargill Inc. v. Budine*, No. CV-F-07-349, 2008 U.S. Dist. LEXIS 46300, at 8-9 (E.D. Cal. June 12, 2008) (*quoting Kamakana*, 447 F.3d at 1179); *see also In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 208 (E.D.N.Y. 2008) (lifting seal on documents produced under protective order only after they were subsequently cited in Court's summary judgment order). Accordingly, the public has no interest in Amylin's and Lilly's confidential materials.

III. CONCLUSION

Compelling reasons outweigh any public interest in the materials and justify sealing limited portions of the documents at issue. For these reasons, and for the reasons set forth in the accompanying Declarations, Amylin and Lilly respectfully request that their Motion be granted.

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Dated: August 21, 2015

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SIGNATURE ATTESTATION

Pursuant to Section 2.f.4 of the Court's CM/ECF Administrative Policies, I hereby certify that authorization for the filing of this document has been obtained from each of the other signatories shown above and that all signatories have authorized placement of their electronic signature on this document.

/s/ Amy J. Laurendeau